

## SEARCH REQUEST FORM

4-735

Examiner # (Mandatory): 76197Requester's Full Name: Gurlene A. GabelArt Unit 1641 Location (Bldg/Room#): 7D16 C11Phone (circle 305/306/308) 308Serial Number: C9/087871Results Format Preferred (circle): PAPER DISK E-MAILTitle of Invention Automated Diagnostic System Implementing Immunoassays, Clinical Chemistry Inventors (please provide full names): Gerald Wagner, Acqdg to Reflex AlgorithmEarliest Priority Date: 6-2-98Keywords (include any known synonyms, registry numbers, explanation of initialisms): (Analyzer or Instrumentation)Diagnostic System: Immunassay Analyzer Clinical Chemistry Analyzer Hematology Analyzer local processorsProcessor = program = reflex algorithmNetwork = private or public(Biochemical/Biological) marker measurement:⇒ concentration level (or activity) level⇒ predetermined significance of biochemical markers(Automation/Automatic Execution)Computer program = first code → instructioncommunication code

## Search Topic:

Please write detailed statement of the search topic, and the concept of the invention. Describe as specifically as possible the subject matter to be searched. Define any terms that may have a special meaning. Give examples of relevant citations, authors, etc., if known. You may include a copy of the abstract and the broadcast or most relevant claim(s).

See claim 1, 9, 10, 13, 16

Point of Contact:  
 Beverly Shears  
 Technical Info. Specialist  
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## STAFF USE ONLY

Searcher: Beverly C 4994 Type of Search

- Vendors (include cost where applicable)

Searcher Phone #:

 N.A. Sequence SJN

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Date Picked Up:

 Structure (#) Lexis/NexisDate Completed: 05-05-99 Bibliographic WWW/InternetClerical Prep Time: 12 Litigation In-house sequence systems (list)Terminal Time: 28 Fulltext DialogNumber of Databases: 1 Procurement Dr. Link Other Westlaw ..Other (specify)

BEST AVAILABLE COPY

**Gabel, Gailene**

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**To:** STIC-ILL  
**Subject:** 09/087,871

Please provide a copy of the following literature:

1) AZIZ D et al., REFLEXIVE ALGORITHMIC APPROACH TO CLINICAL DECISION-MAKING - BREAST-CANCER AS A MODEL, JOURNAL OF CELLULAR BIOCHEMISTRY, (1993) Supp. 17G, pp. 247.

Thanks a bunch,  
Gailene R. Gabel  
7B15  
305-0807

POSTER ABSTRACTS

**Quantitation of Estrogen and Progesterone Receptors by Immunocytochemical and Image Analyses**

Douglas C. Aziz, MD, PhD and Raj R. Barathur, PhD

Specialty Laboratories, Inc., Santa Monica, CA 90404

**Abstract** The ability to detect estrogen and progesterone receptors by immunocytochemical analysis in formalin-fixed, paraffin-embedded sections has clear advantages over other techniques, including the ability to assay small biopsy specimens, fine needle aspirate samples, and archival material. Twenty-two cases of breast carcinoma were evaluated for estrogen and progesterone receptors by immunocytochemical analysis and enzyme immunoassay. Using a true color-based image analysis system, histograms of area versus the optical density of the positive staining nuclei were generated. A binary decision algorithm was derived from these histogram parameters by the Classification and Regression Trees (CART) computer program. Estimates generated by the algorithm for image analysis/immunocytochemical analysis had a 90% concordance with the enzyme immunoassay values. We conclude that quantitative immunocytochemical results for estrogen and progesterone receptor content in formalin-fixed, paraffin-embedded tissue can be generated using image analysis. © 1993 Wiley-Liss, Inc.

**Reflexive Algorithmic Approach to Clinical Decision Making: Breast Cancer as a Model**

Douglas C. Aziz, MD, PhD and Raj R. Barathur, PhD

Specialty Laboratories, Inc., Santa Monica, CA 90404

**Abstract** The number of tests available for the prognostication of patients with breast cancer, (e.g., estrogen and progesterone receptor, DNA ploidy, % S-phase analysis, HER-2/neu, EGFR, p53, cathepsin D, ps2, PCNA, etc.) is staggering. Many published studies statistically prove the prognostic significance for each independent test, but the situation becomes confusing and empirical for the clinician making a decision for a particular patient, particularly when test utilization and cost considerations must be weighed into the equation. Other factors such as the pathological stage, histological grade, vascular and lymphatic invasion, and the age and wishes of the patient should all be taken into consideration in arriving at the optimal treatment protocol. We have applied a Bayesian probability approach to published data in order to derive a branched tree algorithm to predict the survival rates for both lymph node-positive and lymph node-negative women with breast cancer. Specimen quality and test results suggested which subsequent tests were most clinically useful. The size of the algorithm was reduced to minimize the number of tests requested and thus reduce costs. This type of analysis is necessary to ensure that the most information is obtained at the lowest cost, and serves as a model for other diagnostic situations. © 1993 Wiley-Liss, Inc.